

Exhibit A

Defendants' Proposed Additional Instructions Relevant to "Unlawful Conduct"

Unlawful Conduct—Distribution

There are two regulations at issue in this case.

The first regulation includes a list of security requirements for registered distributors who ship controlled substances to pharmacies. It provides that substantial compliance with the standards set forth in the regulation may be deemed sufficient. These security requirements include that a registered distributor shall design and operate a system to identify suspicious orders of controlled substances placed by pharmacies and shall inform the U.S. Drug Enforcement Administration of suspicious orders when discovered by the distributor.

Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

This regulation does not pertain to the filling of prescriptions for patients; it pertains only to shipments to pharmacies by registered distributors.¹

¹ 21 C.F.R. §§ 1301.71(a)-(b), 1301.74(b).

Unlawful Conduct—Dispensing

The second regulation at issue in this case applies to the filling of controlled substance prescriptions for patients. It states that a doctor, or other registered prescriber, may only issue a controlled substance prescription for a legitimate medical purpose in the usual course of her or his professional practice.

It further provides that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

It states that a person who knowingly fills a prescription that was not issued by a doctor or other prescriber for a legitimate medical purpose in the usual course of the prescriber's practice shall be subject to penalties under the Controlled Substances Act.²

² 21 C.F.R. § 1306.04(a).

Unlawful Conduct—Substantial Compliance

The two regulations at issue in this case do not require strict compliance. Only substantial compliance is required.³

Not every act that is in violation of the two regulations I have described to you can cause a public nuisance. Only unlawful conduct that causes a significant interference with a public right to health or safety can be a public nuisance.⁴

³ Dkt. 3913 at 5 (citing 21 C.F.R. § 1301.71(b); OAC-4729-9-05); *see also id.* at 6 & n.8.

⁴ OJI 621.09 Regulated activity, cmt.; RESTATEMENT (SECOND) OF TORTS § 821B, cmt. f; *Brown v. Scioto Cty. Bd. of Commrs.*, 87 Ohio App. 3d 704, 713 (1993).